

REMARKS/ARGUMENTS

In response to the Final Office Action mailed December 2, 2003, Applicants propose to amend their application and request reconsideration in view of the proposed amendments. In this amendment, Claims 37, 43, 45 and 46 are proposed to be amended, Claims 1-36 and 44 were previously cancelled without prejudice and no claims have been added so that Claims 37-43 and 45-46 are currently pending. No new matter has been introduced.

Claim 45 was objected to for a minor informality. Applicants have amended the claims to correct the informality.

Claims 37-40 and 46 were rejected as being anticipated by U.S. Patent Number 5,993,481 to Marcade et al. (Marcade). This rejection is respectfully traversed.

Anticipation exists only if all of the elements of the claimed invention are present in a system or method disclosed, expressly or inherently, in a single prior art reference. Therefore, if it can be shown that there is one difference between the claimed invention and what is disclosed in the single reference, there can be no anticipation.

The present invention as claimed in independent Claims 37 and 46 are directed to graft systems. The graft system of Claim 37 comprises a one-piece tubular graft component having three portions. The middle portion includes a plurality of independent gripping stents configured to prevent migration of the graft. The graft system of Claim 46 includes first and second one-piece graft segments. The graft components define a single flow channel.

Marcade discloses modular bifurcated intraluminal grafts. The modular system includes a base member and one or more grafts connected thereto. More specifically, the specification defines the term "modular" as referring to the fact that the system includes a number of individual components, which may be separately delivered by intraluminal techniques to the aneurysm site and then interconnected with one another *in situ* to form the bifurcated graft. In one embodiment, the modular system includes a primary graft, a base member and first and

second grafts. The primary graft includes a main tapered portion and an annular sleeve. The first and second grafts comprise generally cylindrical tubular constructions. The base member is a hollow generally Y-shaped structure formed by a frustoconical main body which branches into two legs. Each of the grafts consist of an outer layer which is supported along substantially its entire length by an expandable stent. It is specifically disclosed that the outer graft layer is substantially tubular, but can be made tapered. The stent in this embodiment may be self-expanding. The base member is similar in construction to the grafts and includes a flexible outer layer. In another embodiment, the base member has a generally frustoconical main body which gradually decreases in diameter from its distal end to its juncture with an annular sleeve. The main body of the base member is divided into two portions by a web. As with the first embodiment described the base member consists of a flexible outer layer which is supported internally along its entire length by an expandable stent. In yet another alternate embodiment, the base member has a substantially uniform diameter for a major portion of its overall length. The diameter of the base member then gradually increases in a second region. The base member includes a stitch line, which extends in the longitudinal direction in the first region. The stitch line joining the outer layer on the diametrically opposed surfaces of the base member to define two tubular channels. The support stent for this base member may consist of an assembly of several members which independently support the tapered region, tubular channels and the uniform diameter region.

Marcade fails to disclose or even remotely suggest a one-piece structure wherein the structure defines a single flow channel. In each embodiment, the base member has multiple flow channels. Specifically, in the embodiment of Figure 1, the base member comprises a Y-shaped structure. In the embodiment of Figure 6, the base member comprises a web to define two flow channels. In the embodiments of Figures 7 and 8, a stitch line defines the channels. Since Marcade fails to disclose or suggest a single channel device for its base member, there can be no anticipation. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 41-43 and 45 were rejected as being unpatentable over Marcade in view of U.S. Patent No. 6,123,722 to Fogarty et al. (Fogarty). This rejection is respectfully traversed.

U.S. Patent No. 6,123,722 to Fogarty et al. discloses stents and stent-grafts for the treatment of aneurysms. Specifically, Fogarty discloses prosthetic modules, which may be selectively combined to form a composite prosthesis. Also disclosed is a delivery catheter which comprises a tubular cover and a shaft coaxially positioned in the cover. The catheter also comprises a plurality of runners and a nosecone.

Fogarty, as the Examiner suggests, does disclose a bellows like structure. However, Fogarty fails to disclose or even remotely suggest the structure as claimed in independent Claim 37. Therefore, neither reference, whether taken alone or in combination, teaches or discloses all of the claimed elements. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 37-43 and 45-46 were rejected as being unpatentable over Fogarty in view of Marcade. This rejection is respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness.

“To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant’s disclosure. In re Vaeck, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See

MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.”

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

“To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1074). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).”


In making this rejection, the Examiner contends that the tubular graft component illustrated in Figure 3 is similar to the graft component claimed in the present invention. This contention is incorrect. The present invention as claimed in independent Claims 37 and 46 comprises one-piece graft segments comprising a plurality of stent segments. The stent segments are positioned in a one-piece graft component. Fogarty fails to disclose a one-piece structure comprising multiple stents. Marcade does not disclose a one-piece structure having multiple stents. What Marcade does suggest is a base member that consists of a stent that may consist of an assembly of several members which independently support the tapered region, tubular channels and the uniform diameter region. Marcade does not suggest multiple independent stents, but rather a stent having an assembly of several members.

For the reasons set forth above, Applicants respectfully submit that the references, whether taken alone or in combination, fail to disclose or suggest the claimed invention. In addition, there is no motivation to combine the references. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

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The amendment raises no new issues and places the application in condition for allowance. Therefore, entry is proper and earnestly solicited.

Respectfully submitted,

By: 
Carl J. Evens
Reg. No. 33,874

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2518
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